Medtronic

Medtronic Ireland Limited
T Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
Ireland
Tel: 01 511 1400
Fax: 01 807 7220
www.medtronic.ie

URGENT FIELD SAFETY NOTICE

MiniMed™ 600 series and 700 series pump systems

Battery status alerts and alarms

Notification

Insulin Pump	Model Number
MiniMed™ 620G Insulin Pump	MMT-1710, MMT-1750
MiniMed™ 630G Insulin Pump	MMT-1714, MMT-1715, MMT-1754, MMT-1755
MiniMed™ 640G Insulin Pump	MMT-1711, MMT-1712, MMT-1751, MMT-1752
MiniMed™ 670G Insulin Pump	MMT-1760, MMT-1761, MMT-1762, MMT-1780, MMT-1781, MMT-1782
MiniMed™ 700G Insulin pump	MMT-1801, MMT-1805, MMT-1850, MMT-1851
MiniMed™ 720G Insulin Pump	MMT-1809, MMT-1810, MMT-1859, MMT-1860, MMT-1867
MiniMed™ 740G Insulin Pump	MMT-1811, MMT-1812, MMT-1861, MMT-1862
MiniMed™ 770G Insulin Pump	MMT-1880, MMT-1881, MMT-1882, MMT-1890, MMT-1891, MMT-1892
MiniMed™ 780G Insulin Pump	MMT-1884, MMT-1885, MMT-1886, MMT-1894, MMT-1895, MMT-1896

October 2024

Medtronic reference: FA1435
EU Manufacturer Single Registration Number (SRN): US-MF-000023100

Dear Healthcare Professional,

You're receiving this letter because our records indicate that one or more of your patients have a MiniMed™ 600 series and/or MiniMed™ 700 series insulin pump. We would like to inform of a communication Medtronic has created for you to share with your patients to reinforce the importance of following their pump's built-in alerts and alarms for battery status, to always carry extra batteries as outlined in the User Guide, and to inform them about situations that may result in shortened pump battery life with the potential for the pump to stop insulin delivery

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significantly sooner than expected. We also wanted to reinforce that support is available if your patients are impacted by this issue and they can contact Medtronic.

Please carefully review the information below and acknowledge that you have received this notification. Thank you for your patience as we work to continuously improve the experience of your patients; their safety is our top priority.

Issue Description:

In some instances, pumps that have been dropped, bumped, or experienced physical impact, may experience damage to internal electrical components, which may result in reduced battery life, causing the battery alerts to occur when less battery life remains than the User Guide states. Even a single drop could result in reduced battery life, either immediately after the drop, or over time, and will continue to affect the pump even after replacing the battery. Affected pumps will still show "Low Battery Pump" alert which is intended to signal that there are up to 10 hours of battery life remaining, however the actual amount of battery life may be significantly shorter. Following the "Low Battery Pump" alert, escalating alerts and sirens may activate. When the "Replace Battery Now" alarm appears, insulin delivery stops. Extended time without insulin delivery can lead to health risks like hyperglycemia or diabetic ketoacidosis (DKA), potentially requiring medical intervention.

Medtronic has received 271 reports of hyperglycemia >400mg/dL or >22.2mmol/L and 22 reports of diabetic ketoacidosis from January 2023 to September 2024 globally potentially related to this issue. There have been no confirmed serious injuries associated with this issue.

Medtronic asks that you inform MiniMed™ 600 and/or 700 series insulin pump users using the enclosed letter.

Actions Required by Healthcare Professionals

- Notify patients of the Field Safety Notice and required steps for them to take.
- Send the enclosed letter to patients
- Complete and return the attached Customer Acknowledgement Form to acknowledge that you have reviewed and understood this notification and have taken all required actions.

Patient Actions:

The enclosed patient letter contains recommended actions for patients to take, including following all alerts and alarms on their pumps, carrying extra batteries with them at all times, being prepared to change their pump battery upon receiving the "Low Battery Pump" alert, and ensuring they have back-up insulin therapy available at all times in their emergency kit.

The Competent Authority of your country has been notified of this action.

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Patient safety is our top priority, and we appreciate your time and attention in reading this important notification. We apologize for any inconvenience. If you have any questions, please contact our Helpline on Tel No: 01 5111 444 option 2 then option 0.

Sincerely,

Federico Gavioli

Sr Vice President Diabetes EMEA & Americas

Medtronic Diabetes

Ohad Cohen M.D.

Global Sr. Medical Affairs Director

Medtronic Diabetes

Enclosure: Pump User Letter